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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,301	05/01/2007	John G. Babish	068911-0169	7158

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EXAMINER	
KANTAMNENI, SHOBHA	
ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
08/19/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mweipdocket@mwe.com

Office Action Summary	Application No.	Applicant(s)	
	10/590,301	BABISH ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4 and 9-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *4, 9-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on 106/09/2010, wherein claims 4 has been amended, and claims 1-3, and 5-8 have been canceled. Applicant's amendment also added new claims 10-13.

Applicant's amendment by deleting claims 1-3, and 8 overcomes the rejections of claims 1-3, and 8 under 35 U.S.C 102(e) as being anticipated by Shahlal et al. (US 6,583,322, PTO-1449).

Applicant's arguments have been considered, but not found persuasive. The rejection of claims 4, and 9 under 35 U.S.C. 103(a) as being unpatentable over Kuhrts (US 2004/0137096, PTO-892) is MAINTAINED. See under response to arguments.

Claims 4, 9-13 are pending and examined herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 4, 10-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment with respect to new claims 10, 11 has been fully considered but is deemed to insert new matter into the claims since the specification as

originally filed does not provide support for the limitation, "wherein the composition comprises about 50 mg to about 7500 mg of the reduced isoalpha acid", and "wherein the composition comprises about 50 mg to about 7500 mg of the isoalpha acid". The original specification discloses that the "composition can be formulated to deliver about 50 to about 7500 mg of hops fraction", and not 50 mg to about 7500 mg of the reduced isoalpha acid, 50 mg to about 7500 mg of the isoalpha acid. See page 16, lines 12-14.

Any claim containing a limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. See MPEP § 2163- § 2163.07(b) for a discussion of the written description requirement of 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4, 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhrts (US 2004/0137096, PTO-892).

Kuhrts teaches pharmaceutical compositions comprising hops extract consisting of iso-alpha acids (IAA), and reduced iso-alpha acids (RIAA) such as iso-humulone, iso-cohumulone, iso-adhumulone, dihydroiso-humulone, dihydroiso-adhumulone of the instant formula, and combinations thereof. It is also disclosed that iso-alpha acids which

are combinations of reduced isoalpha acid(RIAA) and isoalpha acid(IAA) will be present in an amount of 0.5 % to 10 % by weight in the hops extract. See page 4, paragraphs [0027], [0031]; page 5, paragraph [0034], Example 1, wherein 3 % of Iso-alpha acids are present in the Hops extract; page 6, claims 1-5, 21-26. Kuhrts also teaches administration of a oral formulation of a tablet containing 750 mg of hops extract powder containing 9.4 % of iso-alpha acids. See page 6, EXAMPLE 3.

Furthermore Kuhrts teaches the same method of reducing inflammation as instantly claimed, comprising administering Hops extract consisting of Iso-alpha acids and reduced iso-alpha acids such as iso-humulone, iso-cohumolone, iso-adhumolone, dihydroiso-humolone, dihydroiso-adhumolone. See page 5, paragraphs [0035]-[0038] ; page 7, claims 1, 9,13, 21, 25.

Kuhrts does not expressly teach the ratio of reduced isoalpha acid : isoalpha acid as about 3:1 to about 1:10, in the composition.

Kuhrts does not expressly teach that the composition contains at least 0.1 % of RIAA and IAA individually.

It would have been obvious to a person of ordinary skill in the art at the time of invention to determine or optimize parameters such as effective amounts of the reduced isoalpha acid and isoalpha acid employed in the composition of Kuhrts, to obtain a desired effect such as reducing inflammation.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine the effective amounts of Iso-alpha acid and reduced isoalpha acid employed in the pharmaceutical compositions for methods of reducing

inflammation in which the ratio of reduced isoalpha acid : isoalpha acid is about 3:1 to about 1:10, since the optimization of effective amounts of known agents to be administered is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine the effective amounts of Iso-alpha acid (IAA) and reduced isoalpha acid (RIAA) employed in the pharmaceutical compositions for methods of reducing inflammation as 0.1 % of RIAA and 0.1 % of IAA, since the optimization of effective amounts of known agents to be administered, is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Note: The ratio of RIAA to IAA of the instant claims such as 3:1 to 1:10 as in claim 4 is broad and might read on the ratio of the prior art composition, hops extract. The individual amounts of RIAA and IAA of the instant claims such as at least 0.1 % of the composition as in independent claim 4 includes any amount between 0.1 % to 99 % which is broad and might read on the prior art composition containing hops extract.

Response to Arguments

Applicant's arguments have been considered, but not found persuasive.

Applicant argues that "Applicants submit that they have discovered that compositions of reduced isoaipha acids (i.e., dihydro isoalpha acids) and isoalpha acids, when combined in certain ratios and within that ratio in certain amounts, have unexpected synergistic anti-inflammatory effects. See the entire application as filed and, for example, the title and abstract and Example 4. Accordingly, the claims reflect the finding of synergism. Kuhrts does not teach or suggest the element of "synergy" as claimed or taught by the present invention." These remarks have been considered. It is pointed that synergy was noted at the lower portion of the dose-response curves for RIAA:IAA combinations of 10:1, 1:1 and 1:100, covering RIAA concentration of $2.5x10^{-8}$ to 0.26 µg/mL i.e at less than 0.1 % of RIAA and IAA individually, and synergy was noted at the higher end of the dose-response curve for RIAA:IAA, ratios of 100:1, 3:1, 3:2, 2:3 and 1:10 over RIAA concentration of 0.31 to 68,261 µg/mL i.e synergy is observed at only particular/specific doses, and not at any dose/amount of RIAA and IAA. It is pointed out that synergy is not observed for RIAA:IAA combinations of 1:1 wherein RIAA and IAA individually comprise at least 0.1 % of the composition i.e synergy is not observed at all the ratios of 3:1 to 1:10 wherein RIAA and IAA individually comprise at least 0.1 % of the composition. Thus, the evidence in the examples is not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the ingredients in the claimed method. See MPEP § 716.02(d). Further, RIAA employed is Redihop (rho-iso-alpha acids(RIAA), 29.5-30.5 %, <0.2 % iso-alpha acids) see page 27, paragraph [093], thus all of the specific compounds claimed in claim 4 are not those in which specifically demonstrated synergy in Table 6.

Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art because Kuhrts teaches that the composition comprising iso-alpha acids such as iso-humulone, iso-cohumulone, iso-adhumulone, dihydroiso-humulone, dihydroiso-adhumulone of the instant formula (Genus A), and combinations thereof is useful in reducing inflammation.

Applicant argues that "Applicants not only have discovered specific ratios in which RIAA and IAAs act synergistically (which is an effect greater than the expected sum of the additive effect of each compound taken separately), but they have also discovered ratios at which the mixture of RIAA and IAA act antagonistically. Thus, the applicants have discovered heretofore unknown properties of the claimed mixtures that give rise to unexpected results." These arguments have been considered but not found persuasive as discussed above. Kuhrts reference renders the administration of claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, are inseparable from its compound.

Further, the ratio of RIAA to IAA of the instant claims such as 3:1 to 1:10 as in claim 4 is broad and might read on the ratio of the prior art hops extract composition in the particular synergistic amounts of RIAA and IAA. The individual amounts of RIAA and IAA of the instant claims such as at least 0.1 % of the composition as in independent claim 4 includes any amount between 0.1 % to 99 % which is broad and might read on the prior art composition containing hops extract which contains 9.4 % of iso-alpha

acids such as iso-humulone, iso-cohumulone, iso-adhumulone, dihydroiso-humulone, dihydroiso-adhumulone .

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period, will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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